



Health
Canada Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Registration Decision

RD2010-15

Beauveria bassiana **strain HF23**

(publié aussi en français)

14 October 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada 

HC Pub: 100553

ISBN: 978-1-100-17034-3 (978-1-100-17035-0)

Catalogue number: H1113-25/2010-15E (H1113-25/2010-15E-PDF)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2010

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Registration Decision for *Beauveria bassiana* strain HF23

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, and Regulations, is granting full registration for the sale and use of *Beauveria bassiana* strain HF23 Technical and Balance ES containing the technical grade active ingredient *Beauveria bassiana* strain HF23 to control house flies in poultry production houses.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document: Proposed Registration Decision PRD2010-13 - *Beauveria bassiana* strain HF23. This Registration Decision describes this stage of the PMRA's regulatory process for *Beauveria bassiana* strain HF23, summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-13. This decision is consistent with the proposed registration decision stated in PRD2010-13.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-13 - *Beauveria bassiana* strain HF23 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

What Is *Beauveria bassiana* strain HF 23?

Beauveria bassiana strain HF23 is a fungus which is used as a microbial pest control agent to control house flies in poultry production houses. This fungus causes a fatal disease in insects known as white muscardine disease. The HF23 strain of *B. bassiana* was originally isolated from a house fly in the USA and is reported to be quite specific to house flies and related flies associated with livestock facilities.

The end-use product, Balance ES, is a commercial class insecticide product that contains *B. bassiana* strain HF23 as the active ingredient. While application in poultry production houses may be considered an indoor use, the chicken manure exposed to the application of Balance ES inside the poultry production house is commonly rendered into fertilizer and used outdoors on agricultural crops. Therefore, this outdoor use was also considered in the human health and the environmental risk assessment.

Health Considerations

Can Approved Uses *Beauveria bassiana* strain HF23 of Affect Human Health?

***Beauveria bassiana* strain HF23 is unlikely to affect your health when Balance ES is used according to label directions**

Exposure to *B. bassiana* strain HF23 may occur during handling of Balance ES. When assessing health risks, several key factors are considered: the microorganism's biological properties (e.g., production of toxic by-products), reports of any adverse incidents; its potential to cause disease or toxicity as determined in toxicological studies; and the likely levels to which people may be exposed relative to exposures already encountered in nature to other strains of the microorganism. Toxicology studies in laboratory animals describe potential health effects from large doses for the purpose of identifying any potential to cause disease or toxicity. There were no signs that *B. bassiana* strain HF23 caused any significant toxicity or disease when tested on laboratory animals.

Residues in Water and Food

Dietary risks from food and water are not of concern

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Although Balance ES is intended for use in an indoor environment (i.e., on chicken manure in poultry houses), treated chicken manure is to be rendered into fertilizer and used outdoors on agricultural crops. This agricultural use pattern is the only means for potential residues of the active ingredient to arise on food/feed items. Based on the natural occurrence of *B. bassiana* in cultivated soils, and on the limited and indirect agricultural use of treated manure, it is not expected that the use of Balance ES will significantly increase the natural environmental background levels of this microorganism.

As there are no direct applications to food and as no significant adverse effects were reported in Tier I acute toxicity/pathogenicity studies, the establishment of an maximum residue limit (MRL) is not required for *B. bassiana* strain HF23. As well, the likelihood of residues contaminating drinking water supplies is negligible. Consequently, dietary exposure and risk are minimal to non-existent.

Occupational Risks From Handling Balance ES

Occupational risks are not of concern when Balance ES is used according to label directions, which include protective measures

Workers using Balance ES can come into direct contact with *B. bassiana* strain HF23 on the skin, in the eyes, or by inhalation. For this reason, the label will specify that users exposed to Balance ES must wear waterproof gloves, a long-sleeved shirt, long pants, shoes plus socks and a NIOSH approved respirator/mask with any N-95, P-95, R-95 or HE filter.

For bystanders, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Beauveria bassiana* strain HF23 Is Introduced Into the Environment?

Environmental risks are not of concern

Although Balance ES is intended for use in an indoor environment (i.e., in poultry production houses), chicken manure exposed to the application of Balance ES in the poultry production house may be rendered into fertilizer and used outdoors on agricultural crops. Studies designed to examine the environmental fate of *B. bassiana* strain HF23 were assessed. *B. bassiana* strain HF23 does not remain viable in chicken manure and chicken litter for long periods of time and is unable to grow at temperatures above 35°C. Application to manure and subsequent composting of the manure is expected to significantly reduce the level of viable cells or spores of *B. bassiana* strain HF23 released into the environment.

The effects of *B. bassiana* strain HF23 on birds was examined. No significant adverse effects were observed in birds when *B. bassiana* strain HF23 was administered orally. Rationales were reviewed to waive avian pulmonary/inhalation/injection, wild mammal, freshwater fish, terrestrial arthropod (including honeybee), aquatic arthropod, non-arthropod invertebrate, and plant testing. The rationales were considered acceptable and significant adverse effects to these non-target organisms are not expected.

Value Considerations

What Is the Value of Balance ES?

Beauveria bassiana strain HF23, formulated as the end-use product Balance ES, has value in controlling populations of house flies in poultry production houses.

Application of Balance ES to various surfaces in poultry production houses can control populations of house flies by infecting and killing the adult flies. *B. bassiana* strain HF23 provides an alternative to conventional chemical insecticides and is well-suited for incorporation into integrated pest management programs.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures being proposed on the label of Balance ES to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because of concerns with dermal irritation and with users developing allergic reactions through repeated high exposures to *B. bassiana* strain HF23, anyone handling Balance ES must wear waterproof gloves, a long-sleeved shirt, long pants, shoes plus socks a NIOSH approved respirator/mask with any N-95, P-95, R-95 or HE filter.

Other Information

1. The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

2. Any person may file a notice of objection regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA section of Health Canada's website (Requesting a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA NO. Title

- | | |
|---------|---|
| 1443964 | De Hoog, G.S. 1972. The genera <i>Beauveria</i> , <i>Isaria</i> , <i>Tritirachium</i> and <i>Acrodontium</i> Gen. Nov. Studies in Mycology, No. 1. Baarn, Netherlands. 15 September 1972. DACO 2.7.1. |
| 1644563 | DACOM2.7.1i Origin, derivation and identification of <i>Beauveria bassiana</i> HF23, DACO: M2.7.1 CBI |
| 1644564 | Product Specifications: Bulk Density correction and normal concentration, DACO: M2.9.1 CBI |
| 1644597 | 2008, Covering letter, DACO: 0.8 |
| 1644601 | 2008, PMRA approved label, DACO: M1.1 |
| 1644602 | 2008, DACO M2.10.2 Analysis for Microbial Contaminants, DACO: M2.10.2 CBI |
| 1644604 | 2007, Certificates of Analysis, DACO: M2.10.2 CBI |
| 1644605 | 2008, Certificates of Analysis, DACO: M2.10.2 CBI |
| 1644619 | DACO: 0.0 |
| 1754564 | 2009, Reply to DACO M2.7.1i additional information request, DACO: 0.8.26 |
| 1754565 | 2004, Vegetative compatibility groups in indigenous and mass-released strains of the entomopathogenic fungus <i>Beauveria bassiana</i> : likelihood of recombination in the field, DACO: M2.10.1 |
| 1754566 | 2009, ARSEF listing of <i>Beauveria bassiana</i> , HF23, DACO: M2.10.1 |
| 1754569 | 2009, Reply to Screening Deficiency of March 5, 2009 re: DACO M2.10.2, DACO: 0.8.24 |
| 1754570 | 2009, Clarification Responses to DACOM2.10.2, DACO: M2.10.2 CBI |
| 1754571 | 2008, 5-lot analysis CoA No. RES-325/3468 Page 1 of 2, DACO: M2.10.2 CBI |
| 1754572 | 2008, 5-lot analysis CoA No. RES-325/3468 Page 2, DACO: M2.10.2 CBI |

1780143 2009, DACO: 0.8 Correspondence with the applicant

B. Additional Information Considered

i) Published Information

1.0 Chemistry

1703241 Castrillo LA et. al, Strain-specific detection of introduced *Beauveria bassiana* in agricultural fields by use of sequence-characterized amplified region markers, *Journal of Invertebrate Pathology* 82, DACO: M2.7.1

1708138 Bidochka, M.J., McDonald, M.A., St. Leger, R.J., Roberts, D.W., 1992, Differentiation of species and strains of entomopathogenic fungi by random amplification of polymorphic DNA (RAPD), Springer Berlin/Heidelberg, Vol. 25, Number 2/February 1994, DACO: M2